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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,296	11/14/2003	Tinya Abrams	PC23579A	8864
28940	7590	09/07/2007		
PFIZER INC 10555 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			EXAMINER GEMBEH, SHIRLEY V	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/712,296	ABRAMS ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10,17 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,17 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The response filed March 02, 2007 presents remarks and arguments to the office action mailed December 12, 2006. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed March 31, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **Status of Claims**

Claims 1 and 17 have been amended. Claims 1-10, 17 and 21-25 are now pending.

Claims 11-16, and 18-20 have been cancelled.

Allowable Subject Matter of claims 21-25 is withdrawn based on the rejection below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

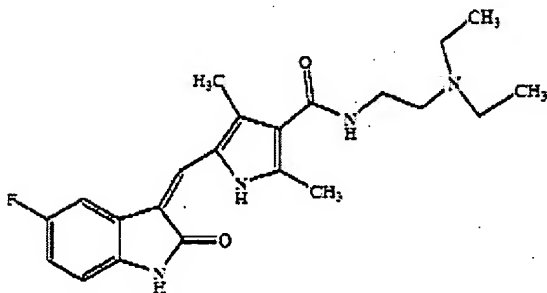
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claims 1-4, 6-9, 17 and 21 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Abrams et al., Molecular Cancer Therapeutics.

Abrams et al. teach SU11248



known as sunitinib, N-[2-

(diethylamino)ethyl]-5-[(Z)-(5-fluoro-1,2-dihydro-2-oxo-3H-indol-3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide, is used for treating small lung cell cancer. See page 471-abstract wherein R1 is a halogen, p is 1, R2 is an alkyl and q is 2, and Z is NR3 and R4, as required by claims 1-4, 6-9, 17,21 and 23, in combination with cisplatin (see underlining page 475) as required by the instant claims. Administering to a patient is shown on page 372, rt. col.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

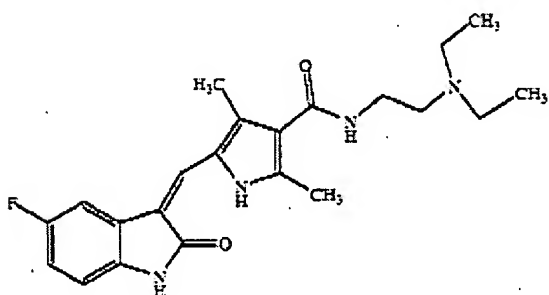
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 17 and 21-25 are rejected under 35 U.S.C. 103(a) as being obvious over Abrams et al., Molecular Cancer Therapeutics, in view of Tang et al., US 6573293 (already of record) and Goodman and Gilman, Pharm. 9<sup>th</sup> Ed. Pharmacological Basis of Therapeutics.

Abrams et al. teach SU11248 is an indolinone, a tyrosine kinase inhibitor



known as sunitinib, *N*-[2-

(diethylamino)ethyl]-5-[(*Z*)-(5-fluoro-1,2-dihydro-2-oxo-3*H*-indol-3-ylidene)methyl]-2,4-dimethyl-1*H*-pyrrole-3-carboxamide, is used for treating small lung cell cancer. See page 471-abstract wherein R<sup>1</sup> is a halogen, p is 1, R<sup>2</sup> is an alkyl and q is 2, and Z is NR<sup>3</sup> and R<sup>4</sup>, as required by claims 1-4, 6-9, 17, 21 and 23, in combination with cisplatin (see underlining page 475), as required by instant claims. Administering to a patient is shown on page 372, rt. col.

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Abrams et al., however, fail to teach the combination of other chemotherapeutic agents with the claimed compound of instant formula I.

Tang et al., teach tyrosine kinase inhibitors of the formulae shown in col. 100, formula 124 and 127 (see col.s 108-110) to treat protein kinase disorders. The reference teaches the use of these compounds in the treatment of breast and colon cancer (see col. 175, line 66-67) as required by the instant claims. The reference also teaches the compound is a malate salt (see col. 173, line 60), as required by instant claim 10.

Further, the reference teaches using these tyrosine inhibitors in a combination with other antimetabolite chemotherapy (see col. 175, lines 57-67), wherein daunorubicin and doxorubicin are used. One of ordinary skill in the art would have been motivated to use these compounds as they are all tyrosine kinase inhibitors.

One of ordinary skill would have used the teachings suggested by Goodman and Gilman drawn to combination chemotherapy. See page 1225, Table X-1 with different classes of anticancer agents and page 1230. One of ordinary skill in the art would have been motivated to combine the cited prior art of record disclosing the compound of formula I, with other known anti-cancer agents in claims 1, 17, 22, 24 and 25, as suggested by Goodman and Gilman.

One of ordinary skill in the art would have been motivated to combine anticancer active agents, as taught by Goodman and Gilman, with the active compound of Abrams et al., to inhibit small cell lung cancer. Abrams et al. teach the compound of formula I, SU11248, is used in combination for treating small cell lung cancer, and the skilled

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artisan would have expected a successful result from combining other well known anticancer agents that are known in the art for the same treatment.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG  
8/27/07

*Phyllis Spivack*

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**